K072203

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510(k) Summary

SEP 25 2007

Company Ethicon Endo-Surgery, LLC
475 Calle C
Guaynabo, Puerto Rico 00969

Contact Elizabeth Miller
Regulatory Affairs Associate II
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242
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Date Prepared August 7, 2007

Device Name Trade Name: HARMONIC™ 10 cm Combination Hook Blade
Common or Usual Name: Instrument, Ultrasonic Surgical
Classification Name:
(LFL)

Predicate Device HARMONIC™ Dissecting Hook Blade
HARMONIC™ Sharp Curved Blade

Device Description The Harmonic™ 10 cm Combination Hook Blade is a sterile, single patient use instrument consisting of a titanium blade with a non-removable sheath. The working instrument length is 10 cm and the outer shaft diameter tapers from 8.5 mm proximally to 5.5 mm distally.

The Harmonic™ 10 cm Combination Hook Blade must be used with the 5 mm Adaptor or Hand Switching Adaptor and connected to the Harmonic Hand Piece and Generator prior to use.

The Harmonic™ 10 cm Combination Hook Blade is designed for use exclusively with the Harmonic™ Generator 300 (GEN04) and Harmonic™ Hand Piece (HP054), packaged separately. The Harmonic™ Generator 300 System User Manual should be referenced before using these instruments. The Harmonic™ 10 cm Combination Hook Blade allows for the coagulation of vessels up to and including 2 mm in diameter.

Indications for Use The Harmonic™ instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, gynecologic, exposure to orthopedic structures (such as spine and joint space), ENT (Ears, Nose, Throat), and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

Technological Characteristics The HARMONIC™ 10cm Combination Hook Blade is similar in materials and function to the predicate devices HARMONIC™ Dissecting Hook and HARMONIC™ Sharp Curved Blade. The HARMONIC™ 10cm Combination Hook Blade, end effector design is different in that it incorporates a dissection hook and a flat blade.

Performance Data Bench and animal testing was performed to demonstrate the new device performs as intended. The bench test was conducted to evaluate design parameters on the HARMONIC 10 cm Combination Hook Blade device and demonstrate substantially equivalence to the HARMONIC™ Dissecting Hook and HARMONIC™ Sharp Curved Blade. The animal testing used to evaluate this device consisted of a porcine acute study. This study was used to evaluate the use of the device for hemostasis and transection of vessels up to and including 2mm in diameter. The animal studies support the transection of vessels up to and including 2mm in diameter.

HARMONIC™ 10 cm Combination Hook Blade is manufactured with materials that meet the ISO10993-1: Biological Evaluation of Medical Device-Part 1: Evaluation and Testing biocompatibility requirements for the appropriate level of tissue contact. The materials used in these devices are classified as either non-patient contacting or externally communicating device components with tissue or bone contact of less than 24 hours limited patient contacting. All tests were performed in accordance with FDA Good Laboratory Practice regulations, 21 CFR 58. Biocompatibility for both limited patient contacting contacting materials have been established through history of use in other marketed Ethicon Endo-Surgery medical devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ethicon Endo-Surgery, LLC
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Elizabeth Miller, MST, RAC
Regulatory Affairs Associate II
4545 Creek Road
Cincinnati, Ohio 45242

SEP 25 2007

Re: K072203
Trade/Device Name: HARMONIC™ 10cm Combination Hook Blade
Regulatory Class: Unclassified
Product Code: LFL
Dated: August 7, 2007
Received: August 8, 2007

Dear Ms. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K072203

Indications for Use

510(k) Number (if known): _____

Device Name: **HARMONIC™ 10cm Combination Hook Blade**

Indications for Use:

The Harmonic™ instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, gynecologic, exposure to orthopedic structures (such as spine and joint space), ENT (Ears, Nose, Throat), and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072203